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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/666,430	09/21/2000	Delphine Gabrielle Josette Rea	4205.1US	6289

7590

05/21/2003

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EXAMINER

EWOLDT, GERALD R

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 05/21/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/666,430

Applicant(s)

Rea et al.

Examiner

G.R. Ewoldt

Art Unit

1644



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Mar 18, 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 5, 6, 9-15, 28, 29, and 37-39 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 5, 6, 9-15, 28, 29, and 37-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

DETAILED ACTION

1. A request for continued examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. The amendment and remarks, and the substitute specification, filed 3/18/03, have been entered. Applicant's submission of an unexecuted declaration under 37 CFR 1.132 is acknowledged.

2. Claims 30-36 have been canceled.
Claims 37-39 have been added.
Claims 1, 5-6, 9-15, 28-29, and 37-39 are being acted upon.

3. In view of Applicant's amendment, filed 3/18/03, the previous rejections under the first paragraph of 35 U.S.C. 112 for lack of adequate written description have been withdrawn.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1, 5-6, 9-15, 28-29, and newly added claims 37-39 stand/are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for,

the *in vitro* induction of non-responsiveness of MHC-matched clonal T cells to a defined antigen when dexamethasone-treated dendritic cells have been loaded with the same defined antigen, does not reasonably provide enablement for,

in vivo or *in vitro* induction of non-responsiveness of polyclonal T cells to any undefined antigen or the *in vivo* induction of non-responsiveness when an "unwanted T-cell response" is ongoing, for the reasons of record as set forth in Papers No. 6 and 13, mailed 6/29/01 and 9/19/02, respectively.

Applicant's arguments, filed 3/18/03, have been fully considered but they are not persuasive. Applicant argues that, "The description in the response filed October 29, 2001, does not involve an undescribed mechanism, but rather is discussed throughout the Specification."

Applicant is advised that by a mechanism "previously undescribed" it was meant that it appears that the instant invention functions through a mechanism that was undescribed prior to the instant application. Accordingly, the invention functions by a mechanism that must be considered unexpected and thus, unpredictable.

Applicant argues that the unexecuted declaration filed under 37 CFR 1.132 "confirms and extends the practical use of alternatively activated DC for modulation of the alloimmune response and shows that these can induce a prolonged skin graft survival even in a complete MHC incompatible donor-recipient combination."

Applicant is advised that an unexecuted 1.132 declaration cannot be considered and thus, provides no additional support for the invention of the instant claims. However, upon review, it appears that no antigen-loaded DCs were used in the disclosed experiments, thus, it is unclear how said declaration could support the invention of the instant claims. Note that the rejection is based on two key factors. First, the specification fails to disclose precisely how the antigens that induce unwanted T cell responses are established. Second, given that the claims are drawn to a method for preparing a pharmaceutical composition, the specification fails to adequately disclose that the DCs prepared with these unknown antigens would function as a pharmaceutical composition *in vivo*.

6. The following are new grounds for rejection.

7. Claims 1, 5-6, 9-15, 28-29, and 37-39 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

Under *Vas-Cath, Inc. v. Mahurkar*, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in

possession of the invention, and that the invention, in that context, is whatever is now claimed. Further note that under *Lockwood v. American Airlines Inc.* 107 F.3d 1565, 41 USPQ2d 1961 (Fed. Cir. 1997), "Entitlement to a filing date does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed". It would then seem that an obvious corollary would be that adequate written description does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed.

There is insufficient written description to show that Applicant was in possession of "means for reducing IL-12p40 production by said dendritic cell" or "means for causing said dendritic cell to secrete IL-10 in vitro", other than dexamethasone. As said "means" comprise an unknown genus of indeterminant size, one of skill in the art must conclude that the specification fails to disclose an adequate written description or a representative number of species to describe the claimed genus. Likewise, the specification discloses no specific "antigen[s] against which said T-cell response is to be reduced". Again, given the indeterminant size of the claimed "antigen" genus, and in this instance no species of the genus are disclosed, one of skill in the art must conclude that the specification fails to disclose an adequate written description or a representative number of species to describe the claimed genus. See *Eli Lilly*, 119 F.3d 1559, 43 USPQ2d 1398.

8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday from 7:00 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Technology Center

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1600 at 703-872-9306 (before final) and 703-872-9307 (after final).

A handwritten signature in black ink, appearing to read "G.R. Ewoldt". The signature is stylized with a large initial "G" and a long, sweeping underline.

G.R. Ewoldt, Ph.D.
Primary Examiner
Technology Center 1600
May 20, 2003